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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/511,025

04/28/2005

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EXAMINER

CUTLIFF, YATE KAI RENE

ART UNIT

PAPER NUMBER

1621

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/511,025	<b>Applicant(s)</b> MIRABAL ET AL.	
	<b>Examiner</b> YATE' K. CUTLIFF	<b>Art Unit</b> 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 25-54 is/are pending in the application.
- 4a) Of the above claim(s) 25-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 35-54 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of Claims***

1. Claims 25 - 54 are pending.  
  
Claims 1 - 24 have been canceled  
  
Claims 25 - 34 have been withdrawn.  
  
Claims 35-54 are rejected.

### ***Response to Amendment***

2. New claims 35 - 54, submitted June 24, 2008 are acknowledged and entered.

### ***Response to Arguments***

3. Applicant's arguments, see page 7, filed June 24, 2008, with respect to claim 22 have been fully considered and are persuasive. The 112 second paragraph rejection of claim 22, in view of the cancellation of the claim, has been withdrawn.
4. Applicant's arguments with respect to claim 35 - 54 have been considered but are moot in view newly added claims and the new ground(s) of rejection as set out below.

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 35-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maggiolo, A. (US 2,865,937) and Beal, R.E. (US 3,504,038) in view of Sechi, L.A. et al. (Journal of Applied Microbiology 2001), and further in view of Maggiolo, A. (Journal of the American Oil Chemists' Society, 1963) (Maggiolo 2) and Herman (US 5,190,979).

9. The rejected claims cover, inter alia, a method for obtaining ozonized lipids comprising; obtaining an emulsion comprising water and a lipid in a 1-50% relation by volume; passing a gas comprising ozone through said emulsion at a temperature about between 30-50°C, and having a gas flow per-hour rate to lipid volume ratio about

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between 100 and 500; and employing a quality control parameter including at least one of: peroxide index, acid index, aldehyde concentration, and viscosity. The dependent claims identify the lipid, the gas, the reaction apparatus, the quality control parameters, and identifies the composition of reaction lipid product as primarily alpha-hydroxy-hydroperoxides.

Maggiolo discloses a process for the ozonolysis of unsaturated fatty acids in the presence of water at controlled lower temperatures of 0 to 49°C. (see column 1, lines 20-25 & lines 69-70). The ozonization step is performed by passing an ozone-oxygen or ozone-air mixture into the fatty acid at low temperatures with added water. (see column 2, lines 51-54). Further, Maggiolo teaches that the water and fatty acid in the reaction can be in an equal amount. (see column 2, lines 69-70).

Maggiolo fails to disclose that the oil and water are in an emulsion; the water to lipid ratio of 1 to 50%, the bubbling reactor; the quality control parameters and that the ozonide produced is primarily alpha-hydroxy-hydroperoxides.

However, Beal discloses the ozonization of vegetable oils in a water medium, where the oil and water are in emulsion; a mixture of ozone and oxygen were continuously introduced at a rate of 2.4 standard cubic feet per minute; and reaction temperature is 75 to 100°F (23.8 to 37°C). (see column 2, lines 29-35 & lines 50-56). Further, in Beal the oil to water ration is 1 to 2.

Beals fails to disclose the use of a bubbling reactor; the quality control parameters and that the ozonide produced is primarily alpha-hydroxy-hydroperoxides.

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However, in Beals the production of peroxides is mentioned and catalytic reduction is used to remove the peroxides. (see column 2, lines 66-70).

The derivatives formed by the ozonization of fatty acids are discussed in Maggiolo 2. In the abstract it is stated that the variety of fatty acid starting materials make possible a great variety of straight chain products containing one or two functional groups such as .. hydroxyl... .

With regard to the use of quality control parameters in the ozonization process, Sechi et al. discloses a process for the ozonization of sunflower oil where the standardization of the preparation was carried out according to parameters that included peroxide index indicators in the ranges of 500 and 800 mmol kg<sup>-1</sup> ; acidity index where the value ranged between 6 and 8 units; aldehyde concentration; and viscosity. (see page 280, Materials and Methods).

Lastly, with regard to the use of a bubble reactor, Herman in Example 1, where squalene is ozonized, and ozone generator is used and the ozone gas is bubbled through the solution.

It would have been obvious to one of ordinary skill in the art to prepare an ozonized lipid where the lipid is a vegetable oil, and an ozone containing gas is passed through the water-oil mixture as suggested by the processes of Maggiolo and Beal; further employing quality control parameters as suggested by Sechi to produce an ozonized lipid with the desired activity, i.e. antibacterial and achieve the claimed invention. As disclosed in Sechi et al. the motivation for the process is the fact that

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researches have been driven to study the antimicrobial agent from essential oils. (see page 279, column 2, paragraph 1).

Therefore, the invention as a whole was *prima facie* obvious because a person of ordinary skill in the art at the time the invention was made, would have been motivated to combine the prior art to achieve the claimed invention and that there would have been a reasonable expectation of success.

### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to YATE' K. CUTLIFF whose telephone number is (571)272-9067. The examiner can normally be reached on M-TH 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel M. Sullivan can be reached on (571) 272 - 0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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